



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

NOTICE OF RENEWAL

OF THE

ADVISORY COMMITTEE ON BLOOD SAFETY AND AVAILABILITY

I have determined, after appropriate consultation between this Department and the General Services Administration, that renewal of the Advisory Committee on Blood Safety and Availability (ACBSA) is in the public interest. Performance of duties imposed on the Department by law can best be performed through the advice and counsel of such an advisory group. Continuation of the ACBSA is authorized until October 9, 2006.

I deem that it is not feasible for the Department or any of its existing committees to perform these duties. A satisfactory plan for appropriate balance of committee membership has been submitted.

SEP 8 2004

Date



Secretary of Health and Human Services



CHARTER

ADVISORY COMMITTEE ON BLOOD SAFETY AND AVAILABILITY

PURPOSE

The Secretary is responsible under Sections 301, 351, and 361 of the Public Health Service Act, as amended (42 U.S. Code 241, 262, 264), and various provisions of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 *et seq.*), for carrying out research in health fields including diseases involving blood and blood products, and for issuing and enforcing regulations concerning the collection, preparation, and distribution of blood and blood products, and regulations related to the transmission of communicable diseases. The Advisory Committee on Blood Safety and Availability shall advise, assist, consult with, and make policy recommendations to the Secretary and the Assistant Secretary for Health regarding these broad responsibilities.

AUTHORITY

42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended. The Advisory Committee on Blood Safety and Availability is governed by the provisions of Public Law 92-463, as amended (5 U.S.C. Appendix 2) which sets forth standards for the formation and use of advisory committees.

FUNCTION

The Advisory Committee on Blood Safety and Availability shall provide policy advice to the Secretary and to the Assistant Secretary for Health. The Committee shall advise on a range of policy issues to include: (1) definition of public health parameters around safety and availability of the blood supply, (2) broad public health, ethical and legal issues related to blood safety, and (3) the implications for blood safety and availability of various economic factors affecting product cost and supply,

STRUCTURE

The Committee shall consist of eighteen (18) voting members; twelve (12) public members, including the Chair, selected from State and local organizations, advocacy groups, provider organizations, academic researchers, ethicists, private physicians, scientists, consumer advocates, legal organizations, and from among communities of persons who are frequent recipients of blood or blood products. In addition, six (6) members designated to serve as official representatives of the blood and blood products industry or professional organizations. These representative members shall represent the American Association of Blood Banks, one of the two

major distributors of blood on a rotating basis, a trade organization or manufacturer of blood test kits or equipment, a company that produces leukoreduction processes, a major hospital organization that purchases blood and blood products, and a plasma protein therapeutic association. Where more than one company produces a specified product or process, representatives from those companies shall rotate on the same schedule as public members. All members and the Chair shall be selected by the Secretary, or designee.

The Committee shall also consist of not more than six non-voting ex officio members representing the Office of Public Health and Science, the Food and Drug Administration, the Centers for Disease Control and Prevention, the National Institutes of Health, the Center for Medicare and Medicaid Services, and the Department of Defense.

Members shall be invited to serve for overlapping three-year terms; terms of more than two years are contingent upon renewal of the Committee by appropriate action prior to its termination. Members may serve after the expiration of their terms until their successors have taken office.

Temporary subcommittees consisting of two or more committee members may be established as needed to address specific issues within the Committee's jurisdiction. Subcommittees make preliminary recommendations regarding specific issues for subsequent action by the full Committee. The Department Committee Management Officer will be notified upon establishment of each subcommittee, and will be provided information on its name, membership, function, and estimated frequency of meetings.

MEETINGS

Meetings shall be held no less than once a year with the option of additional meetings at the call of the Chair with the advance approval of a Government official, who shall also approve the agenda. A Government official shall be present at all meetings.

Meetings shall be open to the public except as determined otherwise by the Secretary or other official to whom the authority has been delegated; notice of all meetings shall be given to the public.

A quorum shall be a majority of members who have not been disqualified from participation due to financial conflicts of interest.

Meetings shall be conducted, and records of the proceedings kept, as required by applicable laws and Departmental regulations.

COMPENSATION

Members who are not full-time Federal employees shall be paid at the rate of \$150.00 per day, for time spent at meetings, plus per diem and travel expenses in accordance with Standard Government Travel Regulations. Members who serve as representative of a particular interest group or industry shall serve without compensation, pursuant to advance written agreement, but may be allowed per diem and travel expenses for all Government-directed travel.

ANNUAL COST ESTIMATE

Estimated annual cost for operating the Committee, including compensation and travel expenses for members but excluding staff support, is \$110,200.00. Estimated person years of staff support required is 5.0, at an estimated annual cost of \$504,364.00. This cost shall be equally shared by the Centers for Disease Control and Prevention, the National Institutes of Health, the Centers for Medicare and Medicaid Services and the Food and Drug Administration.

REPORTS

In carrying out its functions, the Committee may be asked to prepare reports on a broad range of subjects. In addition, in the event a portion of a meeting is closed to the public a report shall be prepared which shall contain, as a minimum, the function of the Committee, a list of members and their business addresses, the dates and places of meetings, and a summary of Committee activities and recommendations made during the fiscal year. A copy of the report shall be provided to the Department's Committee Management Officer.

TERMINATION DATE

Unless renewed by appropriate action prior to its expiration, the Advisory Committee on Blood Safety and Availability will terminate on October 9, 2006.

APPROVED:

SEP 8 2004

Date



Secretary of Health and Human Services